

JAN 19 1999

Synthes Posterior Universal Spinal System  
Special 510(k) Premarket Notification – Device Modification  
K984612 – Additional Information

K984612

SYNTHES (U.S.A.)  
1690 Russell Road  
Paoli, PA 19301

(610) 647-9700  
Contact: Jonathan M. Gilbert  
01/06/98

Device: Synthes Posterior Universal Spinal System. This system consists of stainless steel or titanium components and consists of rods, hooks, side-opening screws with collar and variable axis screws with rod and screw connector, collar, locking ring and nut, a trans-connector system, open and closed transverse bars, parallel connectors, Schanz screws, clamp with posterior nut and associated manual surgical instruments.

This system is substantially equivalent to previously cleared Synthes spinal systems and is supported by testing which satisfies the requirements of posterior thoracolumbar and sacral fixation.

When used as a posterior pedicle screw fixation system, the Synthes Posterior Universal Spinal System devices are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

In addition, the Synthes Posterior Universal Spinal System is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L<sub>5</sub> – S<sub>1</sub> vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implants after the attainment of a solid fusion. The levels of pedicle screw fixation for these patients are L3-S2.

When used as a posterior non-pedicle screw fixation system, Synthes Posterior Universal Spinal System devices are intended for scoliotic, lordotic, or kyphotic deformities (such as scoliosis, Schuermann's disease), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), and fractures of the posterior thoracolumbar spine. **In addition, when used with 3.5/6.0mm parallel connectors, the Synthes Posterior Universal Spinal System can be linked to the CerviFix System.**



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

JAN 19 1999

Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Jonathan M. Gilbert  
Senior Regulatory Affairs Associate  
Synthes Spine  
Post Office Box 0548  
1690 Russell Road  
Paoli, Pennsylvania 19301

Re: K984612  
Synthes Posterior Universal Spinal System – 4.2mm side-opening screws  
Regulatory Class: II  
Product Codes: MNI, KWP, and MNH  
Dated: December 16, 1998  
Received: December 24, 1998

Dear Mr. Gilbert:

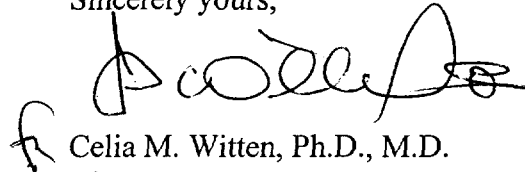
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsma/dsmamain.html>".

Sincerely yours,

A handwritten signature in black ink, appearing to read "C. Witten", with a stylized flourish at the end.

Celia M. Witten, Ph.D., M.D.

Director

Division of General and Restorative Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Synthes Posterior Universal Spinal System  
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510(k) Number (if known): NA

Device Name: Synthes Posterior Universal Spinal System

Indications for Use:

When use as a posterior pedicle screw fixation system, the Synthes Posterior Universal Spinal System devices are intended to provide immobilization and stabilization of spinal segments in skeletally mature patients as an adjunct to fusion in the treatment of the following acute and chronic instabilities or deformities of the thoracic, lumbar, and sacral spine: degenerative spondylolisthesis with objective evidence of neurologic impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudarthrosis).

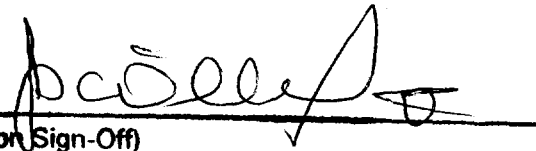
In addition, the Synthes Posterior Universal Spinal System is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L<sub>5</sub> – S<sub>1</sub> vertebra in skeletally mature patients receiving fusion by autogenous bone graft having implants attached to the lumbar and sacral spine with removal of the implants after the attainment of a solid fusion. The levels of pedicle screw fixation for these patients are L3-S2.

When used as a posterior non-pedicle screw fixation system, Synthes Posterior Universal Spinal System devices are intended for scoliotic, lordotic, or kyphotic deformities (such as scoliosis, Schuermann's disease), degenerative disc disease (back pain of discogenic origin with degeneration of the disc confirmed by history and radiographic studies), and fractures of the posterior thoracolumbar spine. In addition, when used with 3.5/6.0mm parallel connectors, the Synthes Posterior Universal Spinal System can be linked to the CerviFix System.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-the-Counter Use \_\_\_\_\_ (Per 21 CFR 801.109)

  
(Division Sign-Off)  
Division of General Restorative Devices  
510(k) Number K984612